Shockwave Medical Announces Japanese Regulatory Approval of Coronary IVL

March 30, 2022

Transformative Shockwave C^2 Intravascular Lithotripsy Catheter Will Soon Be Available in One of the World's Largest Coronary Intervention Markets

SANTA CLARA, Calif., March 30, 2022 (GLOBE NEWSWIRE) -- Shockwave Medical, Inc. (NASDAQ: SWAV), a pioneer in the development of Intravascular Lithotripsy (IVL) to treat severely calcified cardiovascular disease, announced today that the Shockwave C^2 Coronary IVL Catheter received the regulatory approval in Japan.

"Coronary IVL has clearly demonstrated the ability to safely and effectively treat severely calcified coronary lesions in a Japanese population," said Shigeru Saito, MD, FACC, FSCAI, FJCC, Director of the Department of Cardiology and Catheterization Laboratory at the Shonan Kamakura General Hospital in Kamakura, Japan and principal investigator of Disrupt CAD IV, one of the studies used to support approval for Shockwave C^2 in Japan. "Given the safety profile shown to date across multiple studies and calcium morphologies, along with its ease-of-use, I am confident that coronary IVL will offer Japanese physicians a truly unique treatment option for our most challenging patients with calcified lesions."

The approval of Shockwave C^2 was supported by noteworthy 30-day results from the Disrupt CAD IV study, a prospective, multicenter study to assess the safety and effectiveness of IVL in 64 Japanese patients that was published last year in *Circulation Journal*.[i] The study met the primary safety endpoint (freedom from major adverse cardiac events, or MACE, at 30 days) and effectiveness endpoint (procedural success, defined as residual stenosis <50% by QCA without in-hospital MACE) with rates of 93.8 percent, which were consistent with results from the Disrupt CAD III study. From a safety perspective, there were no perforations, abrupt closures, or slow/no-reflow events at any time during the procedures. With all patients receiving intravascular imaging, final stent outcomes showed excellent minimum stent area (5.7 mm^2) and stent expansion at the site of maximum calcification (99.5 percent).

"We are delighted to be partnering with the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) to make this therapy available to the expert cardiologists in Japan," said Doug Godshall, Chief Executive Officer of Shockwave Medical. "With Japan's worldwide leadership in the adoption of intravascular imaging and systematic approach to optimizing lesion preparation, we are confident that CVIT will be the perfect partner to help ensure that coronary IVL will play a vital role in the future calcium treatment algorithms of Japanese physicians."

With the Japan Pharmaceuticals and Medical Devices Agency (PMDA) classifying the Shockwave C^2 Coronary IVL Catheter as a new medical device, Shockwave will now await reimbursement approval from the Japanese Ministry of Health, Labour and Welfare (MHLW).

The Shockwave C^2 Coronary IVL Catheter previously received CE Mark in 2018 and PMA Approval from the U.S. Food and Drug Administration (FDA) in 2021.

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[i] https://doi.org/10.1253/circj.CJ-20-1174

About Shockwave Medical, Inc.
Shockwave Medical is focused on developing and commercializing products intended to transform the way calcified cardiovascular disease is treated. The company aims to establish a new standard of care for the interventional treatment of atherosclerotic cardiovascular disease through differentiated and proprietary local delivery of sonic pressure waves for the treatment of calcified plaque, which the company refers to as Intravascular Lithotripsy (IVL). IVL is a minimally invasive, easy-to-use and safe way to significantly improve patient outcomes. To view an animation of the IVL procedure and for more information, visit www.shockwavemedical.com.

Forward-Looking Statements

This press release contains statements relating to our expectations, projections, beliefs, and prospects, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," and similar expressions, and the negative of these terms. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks, uncertainties, assumptions and other factors that could cause our actual results, level of activity, performance, or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements.

Forward-looking statements contained in this press release include, but are not limited to the following, statements about: the impact of the COVID-19 pandemic on our operations, financial results, and liquidity and capital resources, including the impact on our sales, expenses, supply chain, manufacturing, research and development activities, clinical trials, and employees; our ability to develop, manufacture, obtain and maintain regulatory approvals for, market and sell, our products; our expected future growth, including the size and growth potential of the markets for our products; our ability to obtain coverage and reimbursement for procedures performed using our products; our ability to scale our organizational culture; the impact of the development, regulatory approval, efficacy and commercialization of competing products; the loss of key scientific or management personnel; our ability to develop and maintain our corporate infrastructure, including our internal controls; our financial performance and capital requirements; and our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others. These factors, as well as others, are discussed in our filings with the Securities and Exchange Commission (SEC), including in Part I, Item IA - Risk Factors in our most recent Annual Report on Form 10-K filed with the SEC, and in our other periodic and other reports filed with the SEC. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date hereof to conform these statements to actual results or revised expectations.

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